VIRGINIA:

IN THE CIRCUIT COURT FOR THE CITY OF ROANOKE

TOSHA ANDREWS, ADMINISTRATOR OF THE ESTATE OF SARA D. CULP A/K/A SARA D. ANDREWS, DECEASED,

Plaintiff,

v.

Case No.: CL14-923

INSIGHT HEALTH CORP.,

Serve: National Registered Agents, Inc.
Registered Agent
4701 Cox Road, Suite 285
Glen Allen, Virginia 23060

IMAGE GUIDED PAIN MANAGEMENT, P.C.,

Serve: National Registered Agents, Inc.
Registered Agent
4701 Cox Road, Suite 285
Glen Allen, Virginia 23060

JOHN M. MATHIS, M.D.,

Serve: John M. Mathis, M.D.
2923 Franklin Road, S.W.
Roanoke, Virginia 24014

and

ROBERT F. O'BRIEN, M.D.,

Serve: Robert F. O'Brien, M.D.
2923 Franklin Road, S.W.
Roanoke, Virginia 24014

Defendants.

Filed in the Clerk's Office this 6th day of May 20 14

Writ Tax	$ 25.00	208 Fee	$ 48.00
Fee	$ 290.00	Teste:	229 - $2.00
Ub Fee	$ 4.00	BRENDA S. HAMILTON, CLERK	
123 Fee	$ 20.00		
106 Fee	$ 5.00		
170 Fee	$ 10.00		
147 Fee	$ 1.00		
Total Paid	$ 394.00		DC

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COMPLAINT

EXHIBIT A

Plaintiff Tosha Andrews, Administrator of the Estate of Sara D. Culp a/k/a Sara D. Andrews, deceased, by counsel and pursuant to *Va. Code Ann.* § 8.01-50, hereby moves the court to enter judgment, jointly and severally, against defendants Insight Health Corp. ("Insight"), Image Guided Pain Management, P.C. ("IGPM"), John M. Mathis, M.D. ("Dr. Mathis") and Robert F. O'Brien, M.D. ("Dr. O'Brien")(collectively, "defendants"), on the grounds and in the amounts hereinafter set forth:

Parties and Venue

1. Tosha Andrews ("Plaintiff") was appointed Administrator of the Estate of Sara D. Culp a/k/a Sara D. Andrews in the Circuit Court for the City of Roanoke, Commonwealth of Virginia, on January 2, 2014.

2. Sara D. Culp a/k/a Sara D. Andrews ("Decedent") was Tosha Andrews' grandmother, and died on December 15, 2013 as a result of contaminated medication she received through the acts of the defendants, as described below.

3. Insight is incorporated in Delaware, and its corporate headquarters and principal place of business are in California.

4. Insight regularly conducts substantial business activity in the City of Roanoke, Commonwealth of Virginia, including under the fictitious name "Insight Imaging – Roanoke", and has done so at all times relevant to this Complaint. As used in this Complaint, "Insight – Roanoke" refers to both the physical clinic located at 2923 Franklin Road, S.W., Roanoke, and to the radiology practice that Insight operates there.

5. Insight uses the fictitious name "Insight Imaging – Roanoke" without having registered that fictitious name, in violation of *Va. Code Ann.* §§ 59.1 – 60 and 70.

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6. The fictitious name "Insight Imaging – Roanoke" is actually registered by, and is also used by, IGPM. IGPM is a Virginia professional corporation and has two shareholders and two employees, Dr.'s Mathis and O'Brien. IGPM's principal place of business is located at 2923 Franklin Road, S.W., in the City of Roanoke, Commonwealth of Virginia. Dr.'s Mathis and O'Brien conduct their business and are employed principally in the City of Roanoke.

7. Dr.'s Mathis and O'Brien are employees and/or agents of IGPM, and are licensed to practice medicine in the Commonwealth of Virginia. At all times relevant to this Complaint, they were acting within the course and scope of such employment and/or agency.

8. At all times relevant to this Complaint, Dr.'s Mathis and O'Brien were additionally and/or alternatively employees and/or agents of Insight, and were acting as well and/or alternatively in the course of such employment and/or agency.

9. All defendants are subject to the exercise of personal jurisdiction by this court, and venue is proper in the City of Roanoke.

Background

10. This case is about the decision by all of the defendants in this case, and each of them individually, to inject the Decedent with medication that, because of the circumstances of its origin, production and procurement, was unreasonably and unnecessarily dangerous for such purpose. The medication was injected directly into the Decedent's spinal column, bypassing many or all of her bodies' natural defense mechanisms and going straight into her neurological system, including her brain, with fatal consequences. The defendants chose to do this notwithstanding the wealth of information available indicating the dangerous risks associated with the use of such medication.

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11. The serious risks of pharmacy compounding were the subject of considerable public discussion in the pharmacy community before this healthcare catastrophe took place. For example,

in 2002 (ten years before this outbreak), the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. In that report, the CDC concluded: "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination."

12. On March 24, 2005 (seven years before this outbreak), USA Today published a front page article with the following headline: "Safety concerns grow over pharmacy-mixed drugs." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by license, commercial pharmaceutical manufacturers.

13. In 2006 (six years before this outbreak), the FDA conducted a survey of compounded drug products. They collected 36 samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

14. In May 2007 (five years before this outbreak), the FDA published an article titled: "The Special Risks of Pharmacy Compounding." In that article, the FDA highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice.

15. In 2010 (two years before this outbreak), the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

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16. On November 5, 2010 (about two years before the outbreak), the American Society of Anesthesiologists, the American Society of Health-System Pharmacists (ASHP") and other medical societies published a joint report regarding drug shortages. That report concluded, inter alia, that "Compounding pharmacies may . . . present patient risks; several deaths have been associated with improperly sterilized compounded products."

17. In May 2012 (a few months before this outbreak), the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

18. Notwithstanding the foregoing, the defendants deliberately engaged in acts of battery, fraud, violations of the law, and (alternatively) negligence with moral turpitude, in order to make more money for themselves, all the while placing these plaintiffs, their patients, at great and unnecessary risk (as described in more detail below).

19. Pursuant to Va. Code Ann. § 8.01-53, the beneficiaries of the Decedent's Estate include the Plaintiff Tosha Andrews and others. As a proximate result of the Decedent's death, her beneficiaries have been caused to suffer and incur the following:

a. Sorrow, grief, mental anguish and suffering, and the loss of solace, including society, companionship, comfort, guidance, kindly offices, and advice of the Decedent;

b. Loss of income of the Decedent, and services, protection, care and assistance of the Decedent; and

c. Expenses for the care, treatment, hospitalization and funeral services of the Decedent, incident to her illness and death (collectively, the "Compensatory Damages").

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Count I - Battery
All defendants.

20. The allegations contained in the previous paragraphs are incorporated herein by reference.

21. In June and August 2012, defendants provided image-guided medical treatment to the Decedent at Insight – Roanoke, including one or more image-guided injections of steroid pain medication into her body.

22. As part of such medical treatment, defendants pierced the Decedent's body with a needle and injected the steroid medication.

23. The medication that was injected into the Decedent's body by defendants was "compounded" methylprednisolone acetate ("Compounded MPA"), that Insight had purchased from New England Compounding Pharmacy, Inc. ("NECC"), a compounding pharmacy located in the Commonwealth of Massachusetts.

24. Defendants intentionally concealed from Decedent the fact that the medication being injected into her body was Compounded MPA.

25. Defendant Insight violated and/or facilitated the violation of Virginia law by purchasing Compounded MPA from NECC in bulk, knowing that NECC was not licensed in Virginia or Massachusetts to produce and/or sell Compounded MPA on any basis other than in response to a physician's prescription written for an individual patient.

26. Defendants intentionally and actively concealed from Decedent the fact that she was being injected with Compounded MPA that had been produced and/or sold in violation of Virginia law.

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27. Insight violated Virginia and/or federal law by using the protected health information of patients other than those being injected, to purchase in bulk from NECC the Compounded MPA that was later injected into Decedent's body.

28. Defendants intentionally and actively concealed from Decedent the fact that defendants were injecting Decedent with Compounded MPA that Insight had purchased in bulk from NECC using the names and protected health information of other patients.

29. Defendants otherwise actively and intentionally concealed from Decedent the fact that she was being injected with Compounded MPA: by telling her pre-injection that she was being injected with Depo-Medrol, a brand-name drug manufactured by an FDA-approved and regulated pharmaceutical company; and/or by providing her documentation pre- and/or post-injection that identified Depo-Medrol as the drug with which she would be and/or had been injected; and/or by identifying the injected drug as Depo-Medrol in billing statements sent to the patients and the patients' private and public third-party payers, while at the same time using in such billing statements the National Drug Code (NDC) identifier for methylprednisolone acetate as commercially manufactured (not compounded) by Teva Parenteral Medicines, Inc.; and/or by intentionally producing and providing procedure notes and other records to patients' referring physicians that identified the injected drug as Depo-Medrol; and/or by intentionally altering Insight's IRIS software system such that injections of Compounded MPA were deceptively identified in that software system as injections of Depo-Medrol.

30. Decedent never consented to a procedure involving injection of non-FDA approved Compounded MPA into her body.

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31. Decedent never consented to a procedure involving injection of non-FDA approved Compounded MPA that had been produced, purchased, received, held, delivered and/or sold in violation of Virginia law.

32. Decedent never consented to a procedure involving injection of non-FDA approved Compounded MPA that had been purchased by Insight, in violation of law, in the names of, and by misusing the protected health information of, other patients.

33. Decedent did not consent to the subject procedures or injections. Therefore each of the subject injections was an unconsented touching and thus, a battery.

34. The Compounded MPA in some or all of the subject injections was contaminated with fungus and/or other impurities.

35. As a proximate result of such battery, Decedent died and her beneficiaries have suffered the compensatory damages.

Count II – Fraud
Insight Health Corp.

36. The allegations contained in the previous paragraphs are incorporated herein by reference.

37. At all times relevant to this Complaint, Insight has owned, operated, controlled and held the certificates of public need for Insight – Roanoke and all related imaging equipment.

38. When it purchased the Insight – Roanoke business in or about 2010, Insight contracted with IGPM and Dr.'s Mathis and O'Brien to provide medical services at Insight – Roanoke. The contract documents were drafted by or for Insight to give the misleading and incorrect impression that Insight simply provided consulting services to IGPM. In actuality, Insight controlled the business and operations at Insight – Roanoke, including: hiring, firing and training of technicians and office and other support staff; purchasing supplies; selecting, purchasing and/or

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storing medications including the dangerous, non-FDA approved Compounded MPA, preparing medications for use; record keeping; coding; and billing for medications administered at Insight – Roanoke, including the dangerous Compounded MPA at issue in this case.

39. Beginning in or about 2010 after purchasing the Insight – Roanoke business, Insight implemented a scheme to defraud patients, including Decedent, and their private and/or public third-party payers, including Medicaid and Medicare. The fraud did not come to light until late 2012, after patients who, without their knowledge and/or consent, had been injected with the dangerous Compounded MPA from NECC, began to be diagnosed with fungal meningitis.

40. To further this scheme Insight advertised to the general public that image-guided injections were advertised at Insight – Roanoke and that the medication used in such injections would be the brand name, FDA-approved medications Depo-Medrol and Celestone Soluspan.

41. For Insight's scheme to work, it needed to purchase MPA in bulk and for substantially less than it would have to pay for either Depo-Medrol or generic MPA commercially manufactured by Teva Parenteral Medicines (an FDA-regulated commercial manufacturer).

42. Insight identified NECC as a source of cheap MPA. NECC was an unaccredited, sprawling compounding pharmacy located in Massachusetts that (a) produced its Compounded MPA and other medications in the same complex of buildings as a waste facility; (b) produced the Compounded MPA in bulk batches, increasing the likelihood of mistakes, and despite not being licensed to do so; (c) did not properly sterilize the medications it produced; (d) did not operate with adequate quality control measures; (e) did not operate in a sterile environment; (f) did not have adequately represented samples of Compounded MPA independently tested by an FDA-approved testing facility before releasing them for distribution; and (g) did not comply with United States Pharmacopeia and National Formulary (USP-NF) standards.

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43. In order to procure the Compounded MPA from NECC, Insight prepared "Prescription Order Forms" that it sent to NECC. Rather than complying with applicable law and providing patient-specific prescriptions in order to obtain doses of Compounded MPA designated for the patients identified in each respective prescription, Insight completed the Prescription Order Form by attaching lists containing the names and protected health information of approximately 40 patients who had already received treatment at Insight – Roanoke. Such protected health information included the former patients' names and gender, the names of the patients' referring physicians, medical treatment they received, dates of procedures, times of procedures, file numbers, home telephone numbers, dates of birth, and reasons for exams.

44. In exchange for these 40 names, Insight would then receive 200 vials of NECC's Compounded MPA with each order (a 5:1 ratio of vials to patients). The individual vials arrived in foil pouches, five vials per pouch, with the exterior of the pouch indicating that the contents fulfilled the prescribed requirements for one named patient. Once received by Insight, however, such Compounded MPA was injected into completely different, new patients, including Decedent.

45. When Insight purchase Insight – Roanoke in 2010, Insight installed its Insight Radiology Information System ("IRIS") at Insight – Roanoke. In the IRIS software system, Insight's employees entered coding information for descriptive and billing purposes.

46. At the instruction of one or more of Insight's corporate officers, including but not limited to Executive Vice President Pat Blank, the IRIS was altered so that injections of Compounded MPA were reflected as injections of "Depo-Medrol".

47. On or about the dates of plaintiffs' respective subject injections, Insight, through its employees Karen DeLong or Sharon Boros, used the IRIS system to enter coding information into Decedent's records, establishing a false record that Decedent had been injected with Depo-Medrol.

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In fact, Decedent instead had been injected with Compounded MPA. Insight had performed this same process with hundreds of other patients before the subject injections of Decedent with contaminated Compounded MPA. This is what Insight trained its employees to do.

48. Also using the false information entered into the IRIS system by employees DeLong and/or Boros, Insight or its agents prepared invoices that misrepresented the medication that had been injected into Decedent's body as "Depo-Medrol", the trademarked brand name medication manufactured by Pfizer.

49. By this method of invoicing Insight, including through its employee(s) Karen DeLong and/or Sharon Boros, also intentionally misused and/or misapplied NDC identifier 0703-0051-01 (or an abbreviation thereof). This is the unique code/identifier for Teva Parenteral Medicines, Inc. ("TPM"), an FDA-regulated commercial manufacturer completely unrelated to NECC, for its generic version of 80mg Depo-Medrol. This code/identifier has no connection whatsoever to NECC and/or its unsafe Compounded MPA. Insight specifically trained and instructed its employees, including Karen DeLong and/or Sharon Boros, to miscode Compounded MPA in this manner, in order to conceal the fact that Insight had substituted Compounded MPA for Depo-Medrol and/or TPM's commercially manufactured generic version of Depo-Medrol.

50. Through the same employees, Insight intentionally miscoded Compounded MPA in Decedent's medical and billing records in the IRIS system, using the Healthcare Common Procedure Coding System ("HCPCS") billing J1040. This code is not intended for use with compounded medications.

51. Rather, the non-fraudulent code that should have been provided was J3490, the "unlisted" code.

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52. Insight and its employees and agents uniformly concealed the true nature of the medication that would be, and in fact was, injected into Decedent's body, and misrepresented that the Compounded MPA obtained from NECC and injected into Decedent's body was Depo-Medrol and/or was the generic medication that was commercially manufactured (not compounded) by the FDA-regulated TPM. This concealment of the true nature of the medication that would be, and in fact was, injected into Decedent's body was facilitated by the misrepresentations of Insight and its agents and/or employees, which misrepresentations were false, intentionally made with the knowledge that they were false, and were made with the intention that they be relied on by Decedent, by Decedent's private and public third-party payers, and by Decedent's referring and other treating healthcare providers.

53. Similarly, Dr.'s Mathis and O'Brien, acting for themselves and/or for and on behalf of Insight, created procedure notes for the subject injection(s) of Decedent that misrepresented the injected medication as Depo-Medrol. Insight and Dr.'s Mathis and O'Brien knowingly and intentionally provided such false procedure notes to Decedent and/or Decedent's private and public third-party payers and/or to other healthcare providers, with the knowledge that such notes were false, and with the intent that such persons and/or entities rely on the false identification of Depo-Medrol as the injected drug.

54. Insight, through the previously named employees and others, and through the other defendants, intentionally and actively concealed the fact that it had injected Decedent with a compounded medication that was not preferred by insurers and that Insight had obtained from NECC, an unaccredited compounding pharmacy that was not licensed in Virginia or Massachusetts to produce in bulk and/or to distribute wholesale in Virginia. Insight affirmatively misrepresented that Decedent had been injected with Depo-Medrol.

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55. The facts that Insight concealed and affirmatively misrepresented were material to Decedent's treatment and health. Insight knew that Decedent underwent the subject injections, and knew that Decedent and/or her respective third-party payers paid for the subject injections, on the belief that the concealed facts did not exist. Insight further knew that Decedent relied on it and on the other defendants to obtain and inject into her body medication that was safe. Insight wanted Decedent, her third-party payers, and her other healthcare providers to rely on the nonexistence of the material that Insight deliberately concealed, and on Insight's affirmative misrepresentations that were intended to facilitate the concealment of the true nature of the medication that would be, and was in fact, injected into Decedent's body.

56. These actions by Insight and its employees and/or agents show active and intentional concealment of and affirmative misrepresentations regarding the source and nature of the medication injected into Decedent's body.

57. This active and intentional concealment and misrepresentation by Insight and its employees and/or agents constitutes actual fraud.

58. Decedent's respective private and public third-party payers were agents authorized to receive invoices for medical services, for processing on behalf of Decedent. Therefore, concealment from and misrepresentations to Decedent's third-party payers constitutes concealment from and misrepresentations to Decedent.

59. Insight knew that properly coding the Compounded MPA that had been injected into Decedent's body without her knowledge would have raised concerns and "red flags" with Decedent's and/or others' third-party payers. For example, some patients have at relevant times been insured by Anthem Blue Cross, which states as follows with respect to compounded medications (emphasis added):

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> Compounded medications are customized medication(s) . . . that are not commercially available. . . . However, they are not approved by the U.S. Food and Drug Administration (FDA) nor are they approved by our Pharmacy and Therapeutics process. **Since there is limited oversight in the preparation of these compounded medications, there is a possibility that patients may be put at risk when prescribed a compound that is not subject to quality testing that validates purity, stability or dosage. . . .** Thus, due to the lack of data to adequately review these medications, compounded medications are considered **non-preferred**. . . . they may also require prior authorization of benefits for coverage through a participating network pharmacy. . . .

60. Accordingly, Insight and its employees and agents, as described, and as part of the fraud on Decedent and her third-party payers, intentionally miscoded and misidentified the Compounded MPA injected into Decedent's body, to prevent Decedent and her third-party payers from knowing that Insight had injected Decedent, without her knowledge, with Compounded MPA. Insight did the exact same thing with hundreds of other patients.

61. Insight's fraudulent scheme and prolonged pattern of deception succeeded until approximately September, 2012, when patients in Virginia and elsewhere became ill after being injected with contaminated Compounded MPA from NECC. Until then, Decedent and her third-party payers did not recognize Insight's deception, and Insight was able to continue its practice of purchasing Compounded MPA from NECC and passing it off as a properly manufactured and acquired, FDA-approved, safe medication.

62. Insight's scheme to defraud Decedent and her third-party payers was knowingly and intentionally designed to deceive patients and their third-party payers, in order to enhance Insight's business profits, notwithstanding the substantial increased risk of grievous bodily injury and/or death to the patients who, without their knowledge or consent, were injected with the Compounded MPA obtained from NECC.

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63. As part of its immoral scheme and plan to defraud patients and their third-party payers, including Decedent and her respective third-party payers, Insight prepared a "Consent for Treatment" form that it had Decedent and other patients sign before receiving steroid injections. In the form, Insight falsely represented to Decedent that she would be told about "the risks and benefits to your procedure before it is performed on you." This false representation was made to Decedent by Insight, through its agents and/or employees, with Insight's full knowledge that it was false when it was made.

64. This false representation was a blatant misrepresentation and a lie. Insight knew that it and its agents and/or employees at Insight – Roanoke and elsewhere were concealing, and had no intention of revealing to Decedent or her insurers, among other things, that Decedent would be injected with the dangerous Compounded MPA, that the inferior Compounded MPA was dangerous, that the risks of the inferior, dangerous Compounded MPA to Decedent's health were increased, that the Compounded MPA had been produced in bulk in violation of applicable law, and/or that Decedent would be injected with Compounded MPA that had been purchased illegally, by the misuse of the names and other protected health information of former patients of Insight. As a result of these misrepresentations and deliberate concealments, Decedent did not give consent for her injection(s).

65. Insight knew that if it made full disclosure as promised (falsely) in the Consent for Treatment form, Decedent would have refused to receive the injections and/or would have demanded that Depo-Medrol be used, and Insight's scheme and plan to defraud patients and their third-party payers would be foiled and its illicit profits lost.

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66. As a proximate result of Insight's fraud, Decedent died and her beneficiaries have suffered the compensatory damages.

67. Insight, through its employees and agents, acted with moral turpitude.

68. The facts that Insight intentionally and actively concealed and misrepresented were material. If Decedent had known the facts that Insight concealed from them, Decedent would not have undergone the subject injections and/or would have required Depo-Medrol to be used for her injections.

69. Insight acted knowingly and intentionally to enhance its profits, and acted with reckless disregard of Decedent's rights, and particularly with reckless disregard for the substantially increased risk of grievous bodily injury and/or death posed to Decedent by the injections of Compounded MPA.

70. Decedent relied on the nonexistence of the facts that Insight deliberately concealed from her.

Count III – Punitive Damages
Insight Health Corp.

71. The allegations contained in the previous paragraphs are incorporated herein by reference.

72. Defendant Insight's fraudulent conduct was willful and/or wanton and evinced Insight's conscious disregard for Decedent's rights.

Count IV – Virginia Consumer Protection Act
All defendants.

73. The allegations contained in the previous paragraphs are incorporated herein by reference.

74. Decedent engaged in "consumer transactions" with defendants, as "consumer transaction" is defined in Va. Code Ann. § 59.1-198.

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75. Defendants are suppliers of the Compounded MPA with which Decedent was injected, and of the related medical services.

76. Virginia Code Ann. § 59.1-200, among other things, prohibits suppliers: from misrepresenting goods as those of another; from misrepresenting the source, sponsorship, approval or certification of goods; and from misrepresenting that goods are of a particular standard, quality, grade or model.

77. Defendants willfully violated Va. Code Ann. § 59.1-200 by: actively concealing from Decedent (and other patients as well) that the medication with which she was being injected was not Depo-Medrol; actively concealing the fact that NECC was the source from which the medication with which she was being injected was obtained; and/or affirmatively misrepresenting the notion that the drug with which she was being injected was Depo-Medrol.

78. As a result of defendants' willful violations of Va. Code Ann §59.1-200, Decedent died and her beneficiaries suffered the compensatory damages.

79. Plaintiff is entitled to treble damages and an award of attorneys' fees, costs and expenses incurred in this matter.

Count V (Alternative) – Negligence Per Se
All defendants.

Pursuant to Rule 1:4(k) of the Rules of the Supreme Court of Virginia, plaintiff alleges the following, in the alternative:

80. The allegations contained in the previous paragraphs are incorporated herein by reference.

81. Va. Code Ann. §§ 54.1-3400 et seq. (the "Virginia Drug Control Act", or "VDCA") are statutes enacted for public safety. Among other things, the VDCA is intended to protect the

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public from the release of substandard and otherwise unreasonably dangerous drugs, including medications, into the stream of commerce in Virginia.

82. At all relevant times, Compounded MPA has been a drug subject to regulation under the VDCA.

83. Decedent was a consumer of Compounded MPA (albeit without her knowledge or consent) and thus belonged to the class of persons for whose benefit the VDCA was enacted.

84. Defendants violated the following provisions of the VDCA at a minimum: Va. Code Ann. § 54.1-3457; Va. Code Ann. § 54.1-3410.2; and/or Va. Code § 54.1-3408.01.

Defendants' violations of Va. Code Ann. § 54.1-3457

85. Va. Code Ann. § 54.1-3457 prohibits, among other things, the following; misbranding any drug (§ 54.1-3457(2)); the delivery and/or sale and/or holding of any drug that is misbranded or adulterated (§ 54.1-3457(1), (3)); and/or the receipt in commerce of any misbranded or adulterated drug (§ 54.1-3457(3)).

86. Defendants violated Va. Code Ann. § 54.1-3457(2) when they misbranded and misrepresented, as Depo-Medrol, the Compounded MPA injected into Decedent's body. Defendants made such misrepresentations in Decedent's medical records, in medical bills sent to Decedent's and/or her third-party payers, and on Insight's website.

87. Defendants violated Va. Code Ann. § 54.1-3457(1) by delivering and/or selling to Decedent Compounded MPA that was adulterated.

88. The Compounded MPA that was injected into Decedent's body was adulterated as that term is defined in Va. Code Ann. § 54.1-3461(A) and/or (B) for the following reasons, at a minimum: the Compounded MPA was produced, prepared, packed and/or held under unsanitary conditions whereby it became contaminated with fungal pathogens and other filth and impurities,

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and/or became otherwise injurious to health; and/or such Compounded MPA was represented by defendants to be Depo-Medrol, a drug recognized in an official compendium, but failed to meet the quality or purity standards set forth in such compendium.

89. Defendants also violated Va. Code Ann. § 54.1-3457(1) and/or (3) by receiving the subject Compounded MPA in commerce, by holding it, and/or by injecting Decedent (and hundreds of other patients) with it and charging a fee for such injections.

Defendants' violations of Va. Code § 54.1-3408.01

90. Defendants violated Va. Code § 54.1-3408.01 when they obtained Compounded MPA from NECC using the names and other protected health information of persons to whom defendants did not intend or expect to administer and/or deliver the Compounded MPA.

91. Defendants violated Va. Code § 54.1-3408.01 when they administered such Compounded MPA to Decedent without a valid, written and signed prescription with her name and other information required by statute.

Defendants' violations of Va. Code § 54.1-3410.2

92. Section 54.1 requires compliance with federal USP-NF standards (United States Pharmacopeia and National Formulary, the official compendium for drugs marketed in the United States). Section 54.1-3410.2(H)(2) prohibits the compounding of medications that are copies of commercially available products, except in limited circumstances that do not apply here. Section 54.1-3410.2(E) adopts USP standards for the creation, manufacture and use of compounded products.

93. The Compounded MPA that Insight purchased from NECC was considered a "high risk" product.

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94. Under USP 797 (as incorporated into the VDCA), high risk compounded drugs must be administered to patients within 24 hours after being produced unless frozen or refrigerated. Frozen products must be administered within 45 days, and refrigerated products must be administered within 3 days.

95. Defendants did not keep the subject Compounded MPA frozen or refrigerated at Insight – Roanoke.

96. Defendants were thus required to administer Compounded MPA from NECC within 24 hours after it was produced, unless defendants had stability and sterility testing results indicating that the Compounded MPA would be safe and stable after such 24 hour period.

97. Insight did not receive such stability and sterility test results, yet defendants nonetheless administered Compounded MPA more than 24 hours after such Compounded MPA had been produced.

98. Defendants violated Va. Code § 54.1-3410 by untimely administration of the Compounded MPA and by failing to confirm and/or investigate "beyond use" dating provided by NECC.

99. Defendants also violated Virginia law by purchasing and administering the subject Compounded MPA from NECC when there was no shortage of Depo-Medrol, the FDA-approved and commercially available brand name drug.

100. As a result of defendants' violations of Va. Code § 54.1-3457, 54.1-3408.01 and/or 54.1-3410.2, Decedent died, and her beneficiaries have suffered the compensatory damages.

101. The injuries sustained by Decedent are harms of the type against which the VDCA, including Va. Code §§ 54.1-3457, 54.1-3408.01 and 54.1-3410.2 was designed to protect.

102. Defendants' violations of the VDCA constitute negligence per se.

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103. Defendants negligence as alleged in this count involved moral turpitude within the meaning of Va. Code § 8.01-34.

Count VI (Alternative) – Negligence
All defendants.

Pursuant to Rule 1:4(k) of the Rules of the Supreme Court of Virginia, plaintiffs allege the following, in the alternative:

104. The allegations contained in the previous paragraphs are incorporated herein by reference.

105. Beginning at least in or about 2010, Insight purchased Compounded MPA from NECC.

106. Between approximately May 2012 and September 2012, Insight purchased approximately 1200 doses of 80 mg Compounded MPA from NECC.

107. On or about September 26, 2012, NECC recalled three lots of Compounded MPA it had produced and distributed throughout the United States: Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013 (collectively, the "contaminated lots").

108. Testing conducted after the recall by the United States Centers for Disease Control and Prevention ("CDC") and the FDA identified fungal contamination in the contaminated lots.

109. The 1200 doses of Compounded MPA referred to above came from the contaminated lots.

110. Decedent was injected with Compounded MPA from the contaminated lots.

111. Insight negligently purchased Compounded MPA from NECC, and defendants negligently administered such Compounded MPA to patients, including Decedent, without

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consideration for the dangers associated with compounded drugs and, particularly, preservative-free compounded steroid drugs such as the subject Compounded MPA.

112. Insight negligently purchased Compounded MPA, and defendants negligently administered such Compounded MPA to patients, including Decedent, without investigating NECC in any manner.

113. Insight negligently purchased Compounded MPA, and defendants negligently administered such Compounded MPA to patients, including Decedent, without knowing whether or how compounded drugs differed from drugs sold by FDA-regulated manufacturers.

114. Defendants negligently injected Decedent with Compounded MPA that defendants had not properly refrigerated and that had otherwise not been stored according to accepted "beyond use" standards.

115. Defendants negligently administered to Decedent Compounded MPA that was past its "beyond use" date.

116. Defendants negligently administered Compounded MPA to Decedent when the respective individual medical conditions of Decedent did not require treatment with a medication that was not commercially available from an FDA-regulated manufacturer.

117. Defendants negligently administered Compounded MPA to Decedent without informing her that she was being injected with Compounded MPA.

118. Defendants negligently administered Compounded MPA to Decedent without telling her that the drug used and/or to be used had been obtained from an unaccredited compounding pharmacy.

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119. Defendants negligently injected Decedent with Compounded MPA that had been produced in bulk, and purchased in bulk, in violation of Virginia law.